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Multi-angled approach to characterized formulations of low soluble compounds using *in situ* concentration monitoring

Modern day drug development cycle poses unique challenges for researchers as more and more compounds coming from the drug discovery are low soluble and require novel formulation approaches to improve their bioavailability. This calls for analytical methods that would be API, formulations and media sparing while providing data enabling realistic *in vitro- in vivo* correlations.

Presentation illustrates the multiple applications of a fiber optic instrument µDISS Profiler™ (Pion Inc.) for collecting and evaluating concentration profiles in 1-20 mL of aqueous and biorelevant dissolution media using sub-mg quantities of API. Monitoring concentration in real time makes the µDISS Profiler a tool of choice in many areas of drug development. It is particularly well-suited for studying super saturation phenomena in various dissolution media. The *in situ* measurement does not perturb the metastable soluble species as do sipper systems which cause premature precipitation from the fluid shear. µFLUX™ add-on apparatus allows combination of dissolution and permeability studies giving a unique insight into dissolution/solubility and permeability interplay of complex formulations and allowing to predict outcome of pharmacokinetic studies more accurately. A Zero Intercept Method (ZIM) overcomes some of the challenges associated with real time concentration monitoring of free API fraction being released from nanoparticles.

Biography

Konstantin Tsinman, Director of Science and Research at Pion Inc., joined Pion in 1998 as principle developer of the Parallel Artificial Membrane Permeability Assay (PAMPA) instrument and subsequently the high-throughput methods for measuring solubility. He has been participating in numerous studies expanding the scope of applications for Pion's *in situ* UV fiber-optic instruments. He has co-authored more than 25 articles in primary scientific journals and holds several patents. He received his Ph.D. in Physics in 1994 from the Institute for Metal Physics, Kiev, Ukraine.

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